REMARKS

This paper is filed as a response to the Examiner's Office Action of May 19, 2003.

Original claims 1 through 20 are pending in the instant application. Claims 1 through 20 were rejected under 35 U.S.C. §102(e) for being anticipated both by Palermo et al. (U.S. Patent 6,228,863 B1) and Kaiko et al. (U.S. Patent 6,277,384 B1). Applicant respectfully traverses the rejection.

The Rejection of the Claims Under § 102(e) is Overcome

The Palermo and Kaiko patents disclose an oral dosage form for reducing abuse of an opioid by incorporating an antagonist into the oral dosage form, which only slightly reduces the effect of the agonist, but not to non-therapeutic levels. In addition, the antagonist of the Palermo and Kaiko patents, in oral dosage form, produces an adverse effect in physically dependent abusers. The antagonist of the Palermo and Kaiko patents is also characterized as being completely effective in countering the effect of the agonist when the dosage form is administered parenterally. MPEP §2131 provides:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained...in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQD2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim.

By comparison, and for immediate reference, it is noted that Applicant's base claim 1, directed to Applicant's formulation, and from which claims 2-10 depend, and Applicant's base claim 11, directed to Applicant's method, and from which claims 12-20 depend, read as follows with underlining added for emphasis of those limitations of the claims which are not disclosed in the cited prior art:

> "1. A controlled release, storage stable, pharmaceutical formulation intended for oral administration comprising: an orally active, therapeutic amount of a pharmaceutical composition in controlled release dosage form

and an orally active antagonist to said pharmaceutical composition in sufficient quantity to counteract the effects of said pharmaceutical composition, said antagonist in a dosage form that is only orally effective as an antagonist if it is chewed or crushed before oral administration.

11. A method for reducing the potential harm or abuse possible from a controlled release oral dosage form of a pharmaceutical formulation caused by chewing or crushing said pharmaceutical formulation prior to oral administration comprising: combining a therapeutic amount of an orally active pharmaceutical composition in controlled release dosage form and an antagonist to said pharmaceutical composition in sufficient quantity to counteract the effects of said pharmaceutical composition when taken orally, said antagonist being in a dosage form that is only active orally if it is chewed or crushed before oral administration."

The language of claims 1-20 in the instant application distinguish over Palermo and Kaiko under Section 102(e), because Palermo and Kaiko do not disclose an oral dosage form where the antagonist is not orally active and does not reduce the effect of the agonist when taken orally in a normal fashion. In the present invention, the antagonist is coated with a substance and passes through the body without being absorbed. Only when the coating is broken by crushing beforehand or chewing in the mouth is the antagonist released and becomes orally active. The antagonist is released and available for absorption and at a level that completely counteracts the effects of the agonist. The Palermo and Kaiko patents disclose an oral dosage of an antagonist that is not encapsulated and is always available to be absorbed, but is in only sufficient amount to slightly counter the effects of the agonist, and is not orally active.

The Palermo and Kaiko patents further disclose a method of reducing abuse by causing a mildly aversive experience for an abuser that takes more than the usually prescribed dose, due to the presence of an antagonist of the type disclosed by the Palermo and Kaiko patents. As mentioned above, in the present invention, the antagonist claimed by Applicant only becomes orally active when the coating is broken, making the

antagonist bioavailable. In addition, the method of the present invention, unlike that of the Palermo and Kaiko patents, is not directed to providing an aversive experience for an abuser.

Claims 2-10 are dependent upon independent claim 1 and are thus patentable for the same reasons given above with respect to claim 1 and more so since they add additional limitations.

Claims 12-20 depend upon independent claim 11 and are thus patentable for the same reasons given above with respect to claim 1 and more so since they add additional limitations.

Conclusion

If the Examiner believes a conference with Applicant's attorney would expedite or conclude prosecution of this application, he is cordially invited to contact Applicant's attorney by telephone.

Applicant respectfully submits that claims 1-20, as originally submitted, are clearly allowable for the reasons stated herein and therefore request such allowance.

Respectfully submitted,

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